K041535 1/4

SEP 16 2004

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Lifestand
Rond Point de Rosarge
40, rue Palverne
F-01700 Les Echets - France
Tel: +33(0)4 37 26 27 28
Fax: +33(0)4 37 26 27 29

Date Summary Prepared: June 7, 2004

2. Name of the Device:

LSC Lifestand Compact

3. Common or Usual Name:

Electrical powered standup wheelchair

4. Device Description:

The LSC Lifestand Compact is a powered standup wheelchair. It is propelled and steered by varying the speed of the two back wheels using independent motors. Front castors support the front of the chair and allow indirect steering through the turning back wheels. The system is controlled with a standard e-fix wheelchair controller, with direct user operation through standard wheelchair joystick. Two high quality maintenance-free watertight rechargeable electrolyte gel batteries, connected in series, supply the energy for the system. A Linear actuator drives the seat into seating or standing position. Another linear actuator drives the backrest into an individual seating-inclination. Both linear actuators are also direct user operated through the standard wheelchair joystick.

Chassis:	Rigid, made from treated steel with epoxy resin paint
Tibia support:	adjustable in height and inclination
Seat:	Depth adjustable with cushion
Backrest:	electrically adjustable
Armrest:	Retractable, can be converted to adjustable chest support
Footrest:	Height can be adjusted

Upholstery:	Fire-resistant (M4), washable fabric
Front wheels:	Ø 7" x 1 3/4"
Rear wheels:	Ø 12 1/2" x 2 1/4"
Brakes:	manual by pushing and electromagnetic in the back wheels
User weight:	max. 120kg
Idle weight:	76kg
Batteries:	2x12V, 17Ah, watertight rechargeable electrolyte gel batteries
Driving-motor:	e-fix by Ulrich Alber GmbH + Co. KG – Germany, 24V DC
Linear actuator seat:	Linac LA 31.1
Linear actuator back:	Linac 314210

5. Intended Use:

The LSC Lifestand Compact offers electrical powered seated and standing mobility to users with ambulatory impairments, including people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc.

6. Comparison to Predicate Devices:

The LSC Lifestand is substantially equivalent in design and intended use to the standup wheelchair LCM by LEVO, K963817

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

The following tests where performed on the LSC standup wheelchair to approve its safety:

EN 12184: 1999	Electrically powered wheelchairs, scooters and their chargers - requirements and test methods
EN 12182: 1999	Technical aids for disabled persons- general requirements and test methods
ISO 7176-1: 1999-10-01	Determination of static stability
ISO 7176-2: 2001-06-15	Determination of dynamic stability of electric wheelchairs
ISO 7176-3: 1988-11-15	Determination of efficiency of brakes
ISO 7176-4: 1997-12-15	Energy consumption of electric wheelchairs and scooters for determination of theoretical distance
ISO 7176-5: 1986-03-01	Determination of overall dimensions, mass and turning space
ISO 7176-6: 2001-10-01	Determination of maximum speed, acceleration and deceleration of electric wheelchairs
ISO 7176-7: 1998-05-15	Measurement of seating and wheel dimensions

ISO 7176-8: 1998-07-15	Static, impact and fatigue strength
ISO 7176-9: 2001-10-15	Climatic tests for electric wheelchair
ISO 7176-10: 1988-11-15	Determination of obstacle-climbing ability of electric wheelchairs
ISO 7176-14: 1997-10-15	Power and control systems for electric wheelchairs – Requirements and test methods
ISO 7176-15: 1996-11-00	Requirements for information disclosure, documentation and labeling
ISO/CD 7176-20: 2001-07-06	Determination of the performance of stand-up type wheelchairs
ANSI/RESNA WC/Vol. 2-1998 Section 21	Requirements and Test Methods for Electromagnetic Compatibility of Electric Wheelchairs and Scooters
EN 55011: 1998	Limits and methods of measurement of radio disturbance characteristics of information technology equipment
CISPR 11: 1997	Industrial, scientific and medical (ISM) radio-frequency equipment – Radio disturbance characteristics – Limits and methods of measurement, Amendment No. 1 (1999)
EN 61000-4-2: 1995	Electromagnetic Compatibility (EMC), Part 4: Testing and measuring techniques, Section 2: Electrostatic discharge immunity test
EN 60601-4-3: 1996	Electromagnetic Compatibility (EMC), Part 4: Testing and measuring techniques, Section 3: Radiated, radio-frequency electromagnetic field immunity test
EN 60335 : 1995	Specification for safety of household and similar electrical appliances
EN 50081-1: 1993	Electromagnetic compatibility. Generic emission standard. Residential, commercial and light industry
EN 50082-2: 1996	Electromagnetic compatibility. Generic immunity standard. Industrial environment
EN ISO 10993-5: 1999	Biological evaluation of medical devices. Tests for in vitro cytotoxicity
NFX 41002	Resistance to salt spray fog
NFP 92503	flammability
NFP 92505	flammability
ISO 6941:1984	Textile fabrics. Burning behavior. Measurement of flame spread properties of vertically oriented specimens

8. Discussion of Clinical Tests Performed:

Clinical tests were not performed

9. Conclusions:

Lifestand believes that the LSC Lifestand Compact is substantially equivalent to the predicate and is safe and effective for it's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Lifestand
C/o Carolann Kotula
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K041535
Trade/Device Name: LSC LifeStand Compact
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup wheelchair
Regulatory Class: II
Product Code: IPL
Dated: September 2, 2004
Received: September 3, 2004

Dear Ms. Kotula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #5

510(k) Number (if known): K041535

Device Name: LSC LifeStand Compact

Indications For Use:

The LSC LifeStand Compact offers electrical powered seated and standing mobility to users with ambulatory impairments, including people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc.

Prescription Use X **(Per 21 CFR 801 Subpart D)**	**OR**	**Over-The Counter Use**_____ **(21 CFT 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041535